

PATENT COOPERATION TREATY

REC'D 22 JUN 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

22

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/000223

International filing date (day/month/year)
24.01.2005

Priority date (day/month/year)
23.01.2004

International Patent Classification (IPC) or both national classification and IPC
A61M5/20, A61M5/30

Applicant
THE MEDICAL HOUSE PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000223

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000223

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-32
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-32
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2005/000223

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US 6544234

D2: WO 03097133

D3: US 5681291

D4: WO 0009186

Clarity Article 6 PCT

- 2.1. Although **claims 1,29 and 30** have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, these claims do not meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The relevant subject-matter should be defined in a single independent claim followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT)

- 2.2. **Claim 1** does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempt to define the subject matter in terms of the **result to be achieved** which merely amounts to a statement of the underlying problem.

What are the technical features of the inner housing moveable in a first position, second position and third position?

The technical features necessary for achieving this result should be added.

Inventive Step Article 33(3) PCT

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-32 does not seem to involve an inventive step** in the sense of Article 33(3) PCT.
- 3.1. The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) an injection device (10) comprising (figures 1-19) an outer housing (50) inside which is located:
- a barrel (12)
 - a needle (18) at one end of the barrel, the needle (18) and barrel (12) being such that at least part of the needle is axially moveable in and out of said outer housing (50) but is biased to be normally wholly inside said housing
 - a plunger (28)
 - an inner housing (96) intermediate the outer housing and the barrel and plunger
 - an energy source (94) in communication with said inner housing (96)
 - wherein the inner housing (96) is moveable by the energy source between three positions, namely:
 - a first position (Fig.4) in which the inner housing is in communication with the barrel (30+36) such that, in use, the plunger and barrel are moveable axially so as to move at least part of said needle out of the outer housing
 - a second position (Fig.5) in which the inner housing is in communication with the plunger but not the barrel such that, in use said plunger is moveable axially into said barrel so as to expel medicament through the needle
 - a third position (Fig.15) in which the inner housing is not in communication with the barrel such that, in use the plunger (28) and barrel (12)

The subject-matter of claim 1 therefore differs from this known device in that:

- the inner housing is moveable between a first position in which the inner housing is in communication with the plunger and a third position in which the inner housing is not in communication with the plunger

The problem to be solved by the present invention may therefore be regarded as how to retract the needle into the outer housing.

However, these features have already been employed for the same purpose in a similar injection device (see document D2, Figure 4, the inner housing (8) has no contact with the plunger (26) and the barrel (18)). It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a injection device according to document D1 thereby arriving at an injection device according to claim 1.

3.2. The document D1 also discloses an injection device comprising:

- an inner housing (96) with on radially flexible tag (100) located at the end of a flexible leg (100)
- one of said tag (100) is situated at the forward end of the inner housing (96) and are moveable radially into and out of communication with the barrel (102)
- the tag is substantially L shaped
- the energy source is a spring (94)
- means (112, or cylindrical piece) for allowing the inner housing (96) to move axially only forward with respect to the outer housing (60)
- needle is biased by a spring (56)
- needle, barrel and plunger are removable from said device
- a removable cover (120)

Therefore the solution proposed in **claims 2,3,6,8-13,15-17 and 19-23**, of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

3.3. In **claims 4,5,7,14,18 and 24-28** (tags, compressed gas, guide means, viewing window) a slight constructional change in the injection device of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

3.4. Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 29-32** does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

Further comments

**WRITTEN OPINION OF THE
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International application No.

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4. Claim 32 contains references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.
5. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1 is not mentioned in the description, nor are these documents identified therein.
6. Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
7. The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).